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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,978	04/25/2001	Steven Ball	BET-00/1188	4958

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EXAMINER
KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
1638	11

DATE MAILED: 10/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Applicati n No. 09/719,978	Applicant(s) BALL, STEVEN	
	Examiner Stuart Baum	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *7-12 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,13-15,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 10 is acknowledged. The partial traversal is on the ground(s) that the different groups of Group I and V do not lack a special technical feature relative to one another. This is not found persuasive because the α-1,4 glucanotransferase enzyme of Group V, a third product, is not required to practice the invention of Group I, drawn to a first product and method of its use. Furthermore, the claims do not constitute an advance over the prior art, as indicated below, and thus are not drawn to a special technical feature.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-6, 13-15, and 17-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a nucleotide sequence chosen from the sequence of SEQ ID NO: 1 encoding a protein having α-1,4 glucanotransferase enzyme activity, sequences homologous to

these sequences, and a fragment of a nucleotide sequence chosen from the sequence of SEQ ID NO: 1 encoding a protein having α-1,4 glucanotransferase enzyme activity and complement thereof.

Applicant describes the nucleotide sequence of SEQ ID NO: 1 from *Chlamydomonas reinhardtii*.

Applicant does not describe a nucleotide sequence chosen from the sequence of SEQ ID NO: 1 encoding a protein having α-1,4 glucanotransferase enzyme activity and complement thereof, a sequence from any source which is homologous to this sequence, and a fragment of a nucleotide sequence chosen from the sequence of SEQ ID NO: 1 encoding a protein having α-1,4 glucanotransferase enzyme activity and complement thereof.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide an adequate written description of the claimed invention.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The court also addressed the manner by which genus of cDNAs might be described: "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.* At 1406.

4. Claims 1-6, 13-15, and 17-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims a method for decreasing the activity of α-1,4 glucanotransferase in a plant by somehow modifying the activity of α-1,4 glucanotransferase (Claim 1), including expressing in antisense orientation a nucleic acid encoding an α-1,4 glucanotransferase causing the production of amylopectin enriched in chains containing less than 6 glucose residues.

Applicant teaches isolation of a mutant of *Chlamydomonas reinhardtii* having reduced accumulation of the normal amount of starch by 96% (Example 1 page 19, lines 6-12), isolation and characterization of the polysaccarhides of the mutant *Chlamydomonas reinhardtii* showing a reduction in the chain length of amylose produced (Example 2 page 20, lines 29-33), amylopectin enriched with extra-short glucans isolated from the mutant (Example 3 page 22, lines 19-26), isolation of the starch processing enzymes and analysis of activity on amylopectin of a 62 kD protein identified as an α-1,4 glucanotransferase or D enzyme (Example 4 pages 22-26), characterization of D enzyme external polymerase activity upon external starch chains (Example 4 pages 27-29), prophetic transformation of maize (Example 5 pages 29-31), the role of D enzyme in degradation of maltooligosaccharides by phosphorylase (Example 6 page 31), PCR isolation of genomic sequence encoding the D enzyme of the *Chlamydomonas reinhardtii* (Example 7 pages 32-33), characterization of the conditional expression of the mutation in *Chlamydomonas reinhardtii* under normal and nitrogen lacking conditions (Example 8 page 33-34), and the isolation of the native *Chlamydomonas reinhardtii* gene.

Applicant does not teach amylopectin enriched for starch chains containing less than 6 glucose residues in transgenic plants expressing sense or antisense α-1,4 glucanotransferase constructs with reduced starch branching enzyme activity, i.e. α-1,4 glucanotransferase activity or D enzyme activity. In addition, Applicant does not teach a multitude of fragments or sequence variants from a multitude of sources which would retain α-1,4 glucanotransferase encoding-ability. Furthermore, Applicant does not teach a means of "modifying" enzyme activity directly.

The unpredictability in attempting to engineer modified branching in starch using a transgenic approach is illustrated in the example where constructs carrying an isoform of a starch branching enzyme cDNA in antisense orientation was introduced into potato, neither the amylose content of the starch in the tubers, nor the total starch content of the tubers was altered (Willmitzer *et al.*, Plant Polymeric Carbohydrates, 17/1993, pp. 33-39, page 38 lines 17-21). Another attempt to modify starch using an antisense construct comprising the GBSS II gene from potato resulted in no effect whatsoever on the starch even when the level of GBSS II protein was very low (Kossmann J. *et al.,* Progress in Biotechnology, 10, Proc. Int. Conf. 4/23-26/95 1995, pp. 271-278 on page 275, lines 11-27)

Generally speaking, the possible and most likely presence of uncharacterized multiple isoforms of starch metabolic enzymes expressed in various tissue types of a plant through the developmental phases of growth, especially during storage of starch, and given the polyploidic nature of many crop plants; transformation with a single isoform of a starch metabolic gene is a highly unpredictable factor to consider in any attempt to reduce gene expression using an antisense strategy.

Given the lack of guidance, the absence of working examples in the specification, the breadth of the claims, and the unpredictability in the art, undue trail and error experimentation would have been required by one skilled in the art to transform and regenerate a corn plant with sense or antisense α-1,4 glucanotransferase constructs and evaluate a multitude of non-exemplified regenerated plants with reduced starch branching enzyme activity, i.e. α-1,4 glucanotransferase activity or D enzyme activity, having amylopectin enriched for starch chains containing less than 6 glucose residues. Undue experimentation would have also been required to isolate a multitude of non-exemplified homologues from a multitude of sources, or to obtain a multitude of non-exemplified sequence fragments or variants, and to evaluate their ability to either encode a protein with α-1,4 glucanotransferase activity or to alter amylopectin content in transformed plants.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1-6, 13-15, and 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections.

At Claim 1, lines 3-4, "the activity of an α-1,4 glucanotransferase enzyme is increased or decreased" is indefinite. It is unclear whether increasing or decreasing the activity of the α-1,4 glucanotransferase enzyme is required for the invention.

At Claim 5, line 4, "a nucleotide sequence chosen from the sequence of SEQ ID NO: 1" is indefinite. It is unclear which parts of SEQ ID NO: 1 are to be chosen and which are not.

At Claim 6, lines 1-2, "such as in particular" fails to positively recite required claim elements. It is unclear if the recited plant species required or merely exemplary.

At Claim 13, line 2, "a nucleotide sequence chosen from the sequence of SEQ ID NO: 1" is indefinite. It is unclear which parts of SEQ ID NO: 1 are to be chosen and which are not.

At Claim 5, line 2, "α-1,4 glucanotransferase enzyme" is indefinite. It is unclear whether "said α-1,4 glucanotransferase enzyme" refers to the native gene or the transgene.

At Claim 13, line 2, "SEQ ID NO: 1 and a fragment" is improper Markush terminology. Replace "and" with --or--. See MPEP 2173.05(h).

Claim 17 provides for the use of a nucleic acid comprising a sequence encoding an α-1,4 glucanotransferase enzyme, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 17 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 13-15, and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hubbard *et al.*, WO 97/22703 A2.

The claims are indefinite for the reason discussed supra. In particular, Claims 1-6 are drawn to a DNA sequence encoding an α-1,4 glucanotransferase enzyme and any DNA sequence "homologous" to SEQ ID NO: 1 and encoding a protein having an α-1,4 glucanotransferase enzyme activity, and methods for their use. Claim 13 and dependent Claims 14, 15, and 17-18 are drawn to a nucleic acid comprising any sequence which comprises any "fragment" of SEQ ID NO: 1 of any length, wherein said nucleic acid encodes an α-1,4 glucanotransferase, vectors comprising said sequences, and methods of their use.

Hubbard teaches a method for modifying the length distribution for the chains of starch by reducing the activity of α-1,4 glucanotransferase in a transgenic plant expressing an antisense α-1,4 glucanotransferase construct (see Abstract, page 16 lines 10-13, and Example 5 pages 44-45). The reference discloses all the limitations of the instant claims.

8. All claims are rejected.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Sonya Williams, whose telephone number is (703) 308-0009.

Russell Kallis Ph.D.
September 27, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638